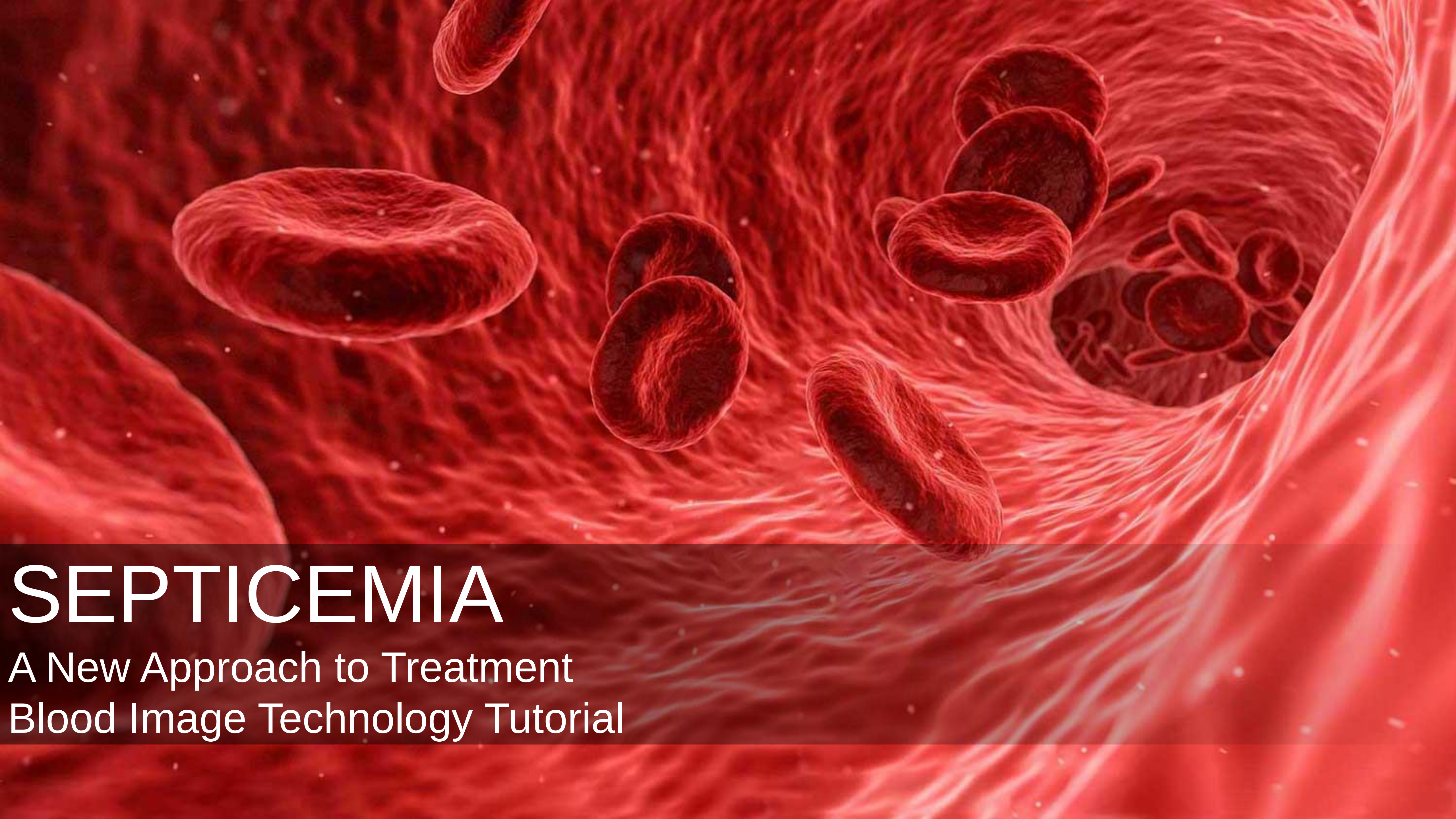


SEPTICEMIA

A New Approach to Treatment

Blood Image Technology Tutorial

The Scale of the Septicemia Problem

Septicemia is a infection of pathogen cells in the human blood stream. Septicemia frequently leads to sepsis, which is the body's life-threatening response to infection. Sepsis can lead to septic shock, which may ultimately result in death.

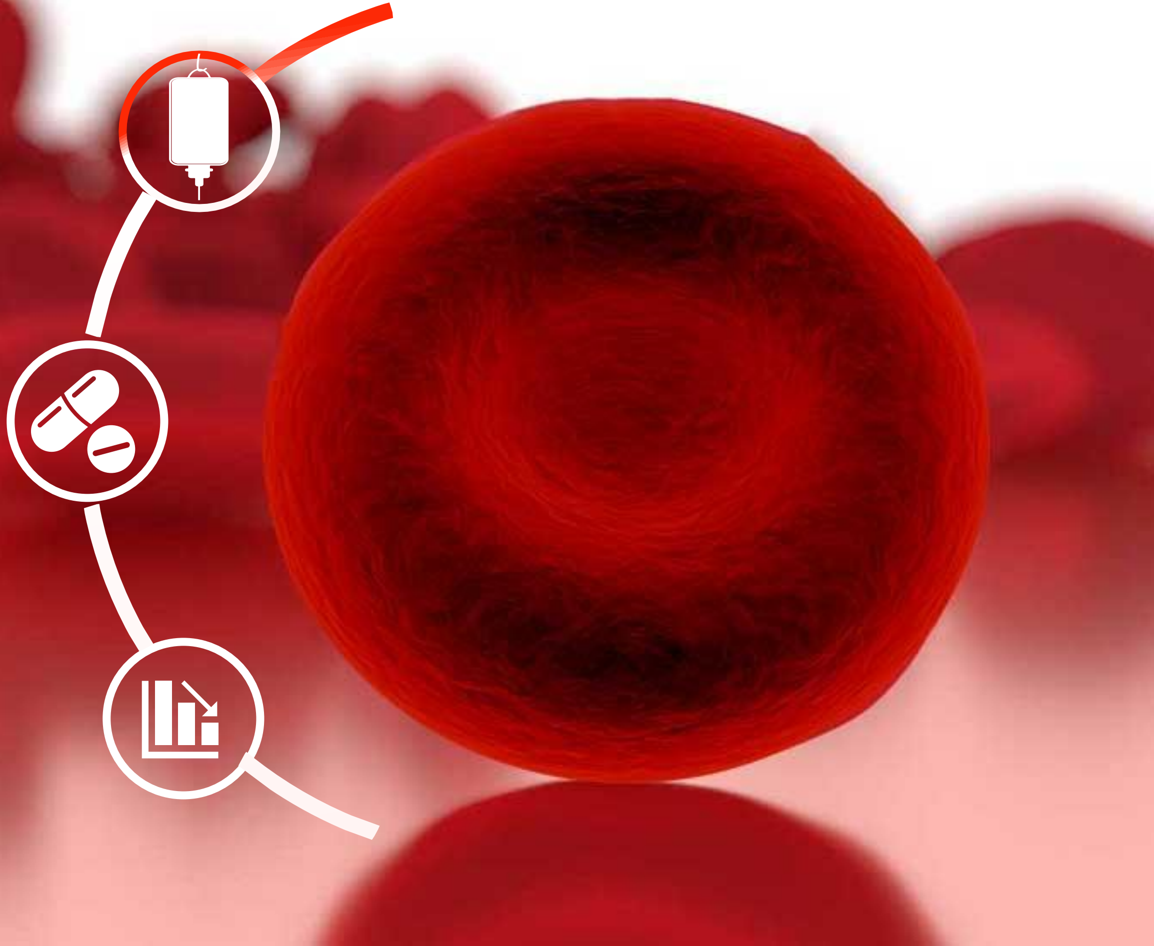
1. According to the Sepsis Alliance, it is the **#1 cause** of death in US hospitals: deadlier than breast cancer, prostate cancer, and AIDS combined.
2. In the US, Sepsis strikes roughly **2 million** people each year and is the cause of **1 in 3** hospital deaths.
3. Worldwide, septicemia is the cause of **1 in 5** deaths.
4. According to the Mayo Clinic, septic shock has a **50%** mortality rate.
5. Sepsis hospitalizations cost Medicare **$41.8 billion** in 2018 alone.

Current Treatment For Septicemia

The 2016 Surviving Sepsis Campaign (SCC) guidelines strongly recommend that the administration of intravenous broad-spectrum antibiotics should be initiated as soon as possible, preferably within an hour of sepsis recognition. (Journal of Thoracic Disease, Mar. 2020)

However, as antibiotic resistance grows, infections are becoming more difficult to treat. Antibiotic resistance is rising to dangerously high levels in all parts of the world. New resistance mechanisms are emerging and spreading globally, threatening our ability to treat common infectious diseases.

A growing list of infections – such as pneumonia, tuberculosis, blood poisoning, gonorrhea, and foodborne diseases – are becoming harder, and sometimes impossible, to treat as antibiotics become less effective. (World Health Organization 31 July 2020)



A New Treatment Approach

Non-Pharmaceutical
Technology-based
Medicine

Technology-based Medicine

Our new approach to the treatment of septicemia (sepsis) does not use any pharmaceutical material, such as an antibiotic.

The technology required for this process is similar in complexity to an ink jet printer and is based on:

- ✓ **current semiconductor and computer manufacturing technology, and**
- ✓ **presently available high speed data processing technology.**

At a high level, this approach comprises removing blood from the patient, processing this blood to kill the pathogen cells, and then returning the processed blood to the patient.

New Septicemia/Sepsis Treatment Process

Image

A lenseless digital picture is produced for a small volume of patient blood. This picture has images of cells present in the blood. These cells have dimensions on the order of microns.

Red blood cells (erythrocytes) are approximate 6 microns in diameter and pathogen cells, such as E. coli, have dimensions of .5 to 3 microns.

Current semiconductor technology can fabricate structures as small as .01 microns, therefore integrated circuit structures to produce images on this scale can be manufactured.

Recognize

After the digital picture, which includes the images of cells in the blood, is produced pattern recognition is used to identify and locate the pathogen cells, such as E. coli. This digital processing utilizes a reference file of cell images to perform the pattern recognition.

Although one picture of imaged blood may contain billions of bits of data, current data processing technology has the capability of performing the pattern recognition in a short period of time.

Destroy

Once the pathogen cells have been located, energy is applied individually to the identified cells to destroy them. This energy can be in the form of ultraviolet light, an electric field, an electric current, or heat, all of which are well known for destroying pathogen bacteria cells.

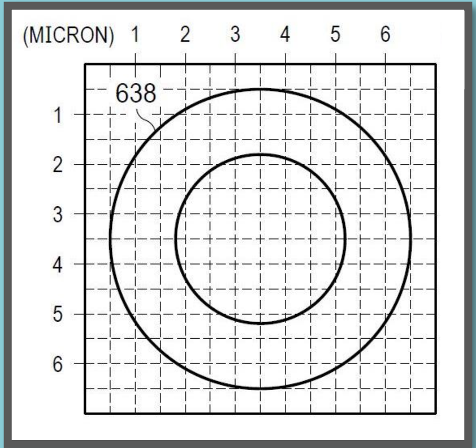
An alternative to applying energy to the identified cells is to vent them from the processed blood, before returning it to the patient.

Repeat

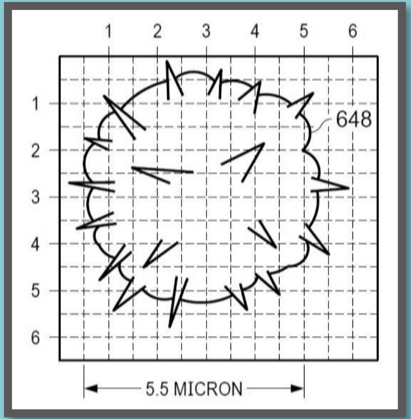
After the first volume of blood has been processed and the identified pathogen cells destroyed or removed, this volume of blood is returned to the patient.

The process is then repeated with a new volume of blood taken from the patient.

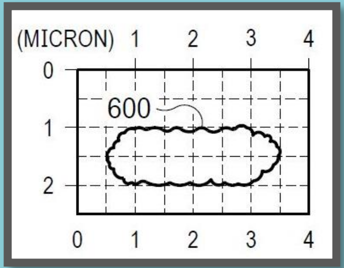
New Treatment Process: Pattern Recognition



Red Blood Cell



White Blood Cell



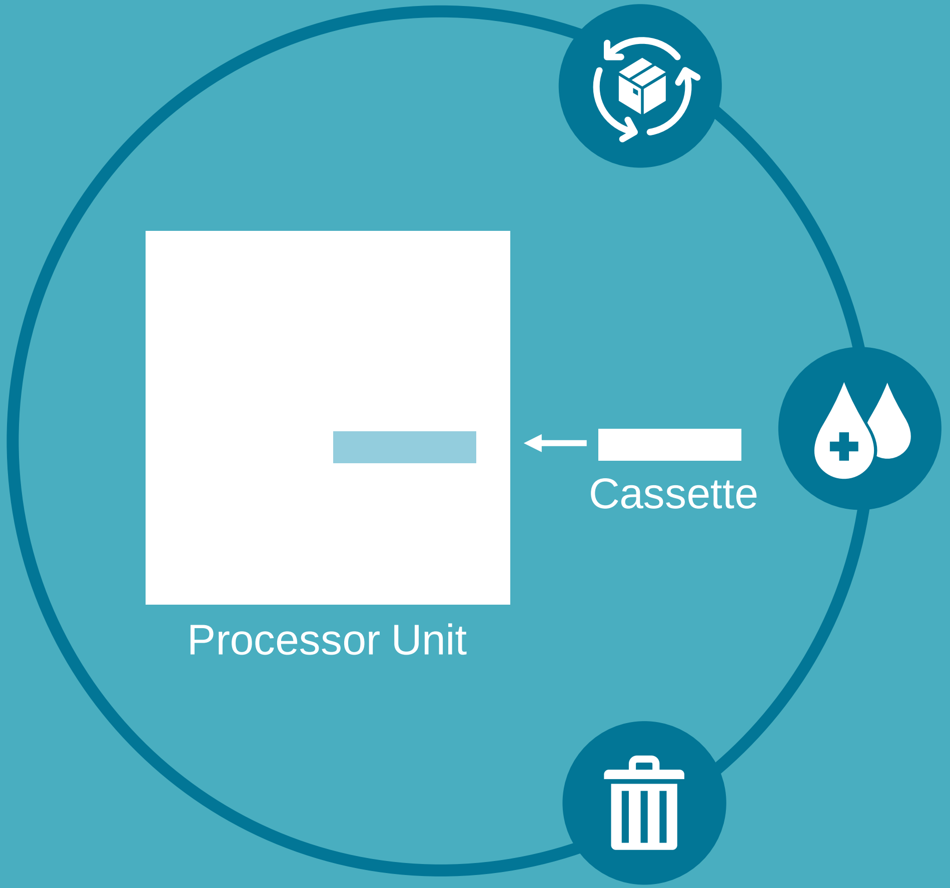
E. Coli Cell

Pattern recognition processing can identify and locate individual pathogen cells (such as E. coli) within a data picture of blood that includes all the cells present in the blood.

New Septicemia/Sepsis Treatment Apparatus

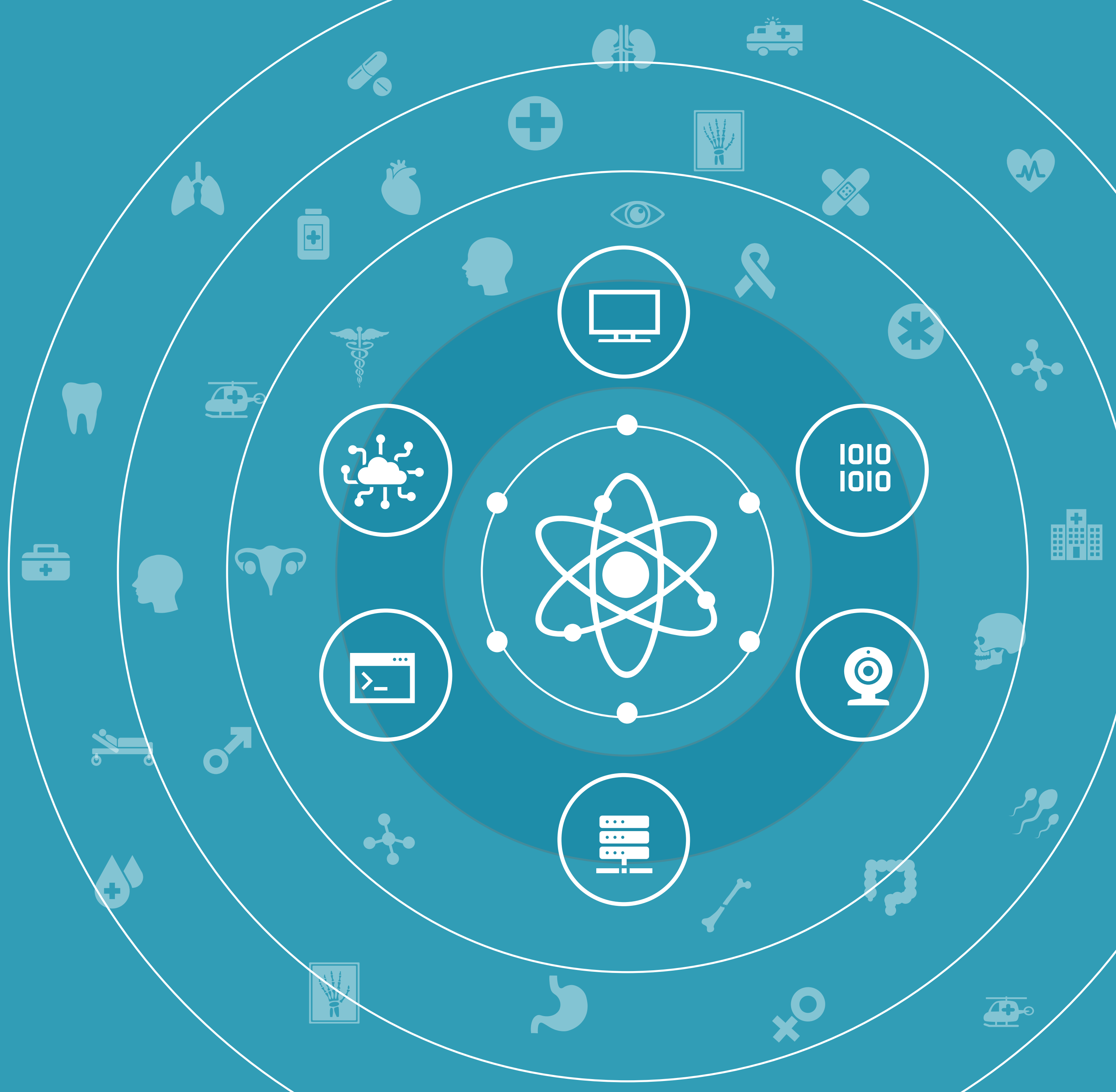
The apparatus for processing comprises two components:

1. a **reusable** electronic processor unit
2. a **disposable** plastic cassette



- ✓ A single plastic disposable cassette unit is used for each patient treatment. The cassette is inserted into the processor unit and is connected by a two-lumen catheter to the patient. A blood pump transfers blood through the catheter from the patient, into the cassette and then back to the patient.
- ✓ Blood in the cassette is processed to destroy the pathogen cells in the blood or to remove the pathogen cells from the blood. The processing continues for a period of time until the concentration of pathogen cells in the blood is reduced to a sufficiently low level to allow the patient to recover from the infection.
- ✓ After the processing procedure has been completed for a patient, the cassette is removed from the processor unit and is disposed of as medical waste.

Apparatus Schematics



Apparatus Overview

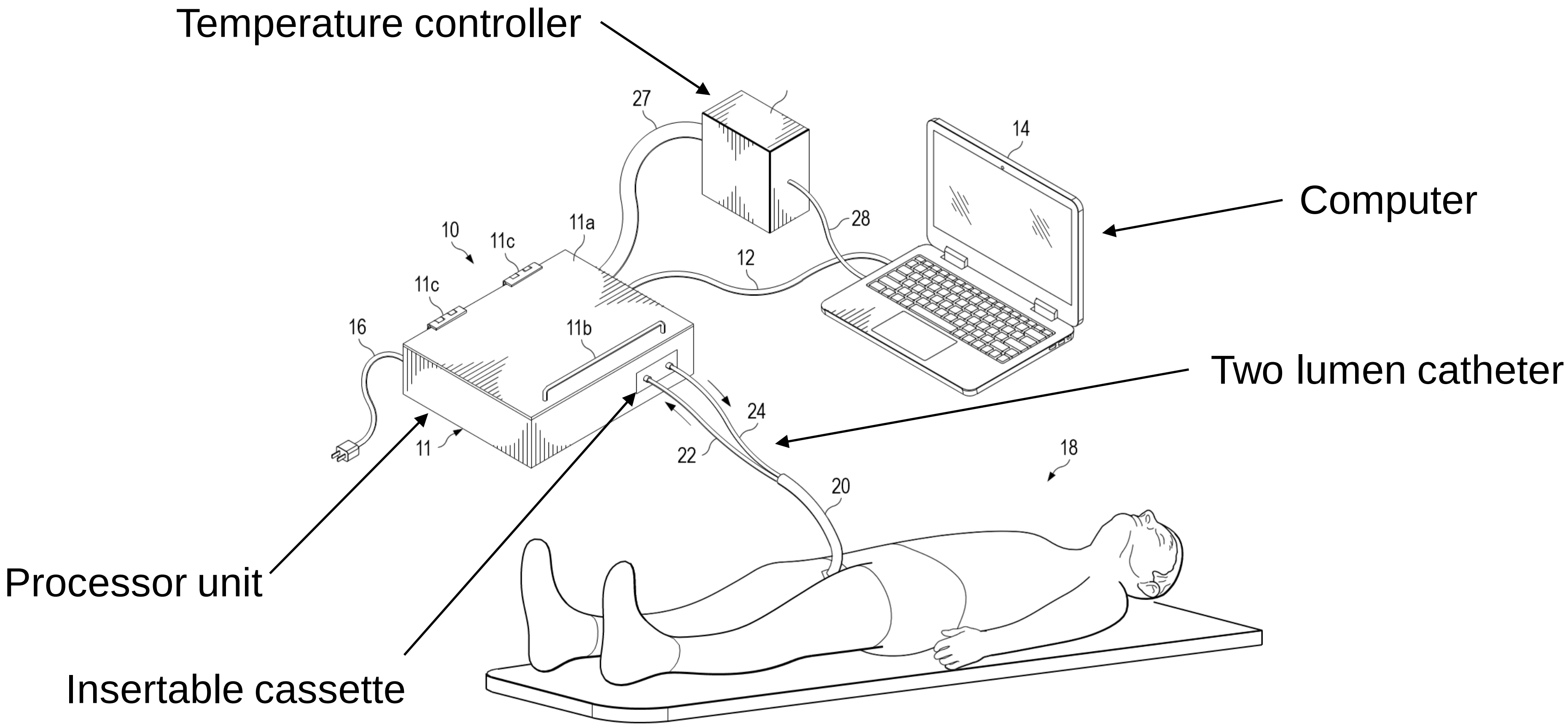


FIG. 1

An overview of the treatment apparatus and a patient: the setup is similar to that of dialysis.

Processor Unit

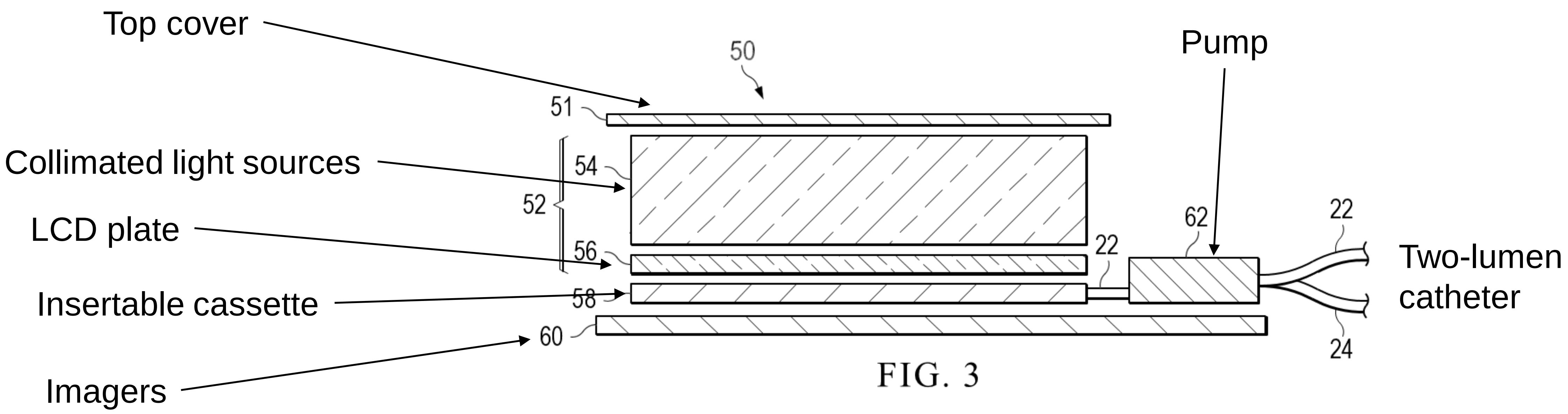


FIG. 3

A cross-section of the processor unit showing the arrangement of the major physical elements.

Cassette Unit

Two-lumen catheter to the patient.

Treatment areas: six columns and five rows shown in this embodiment

Insertable cassette

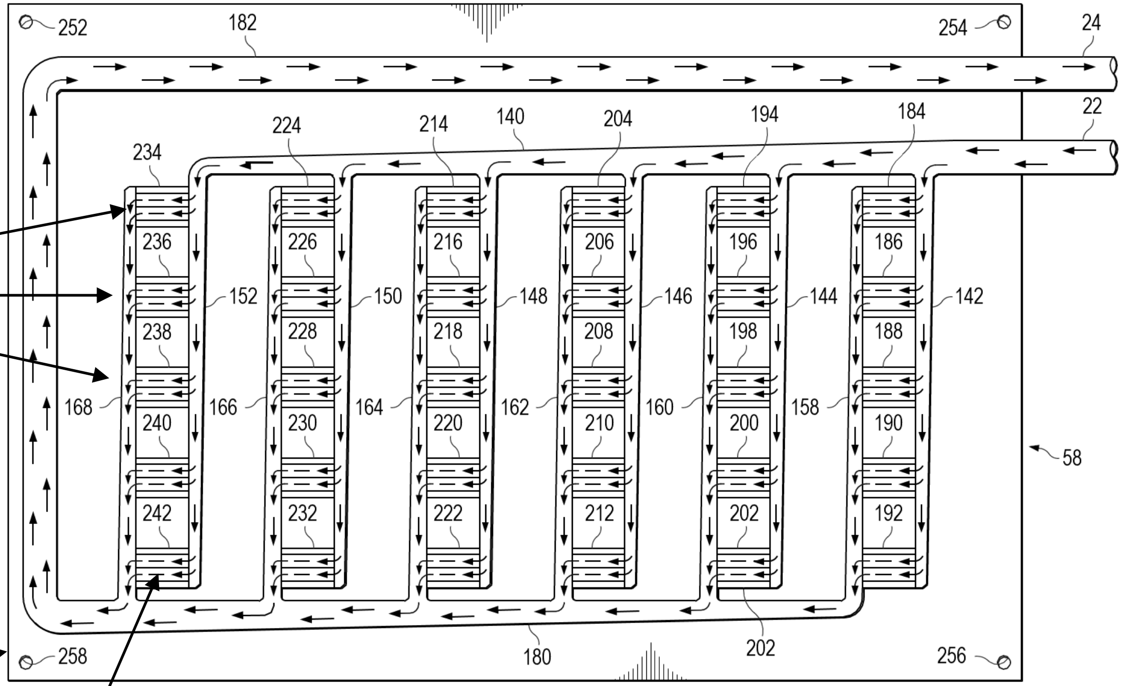
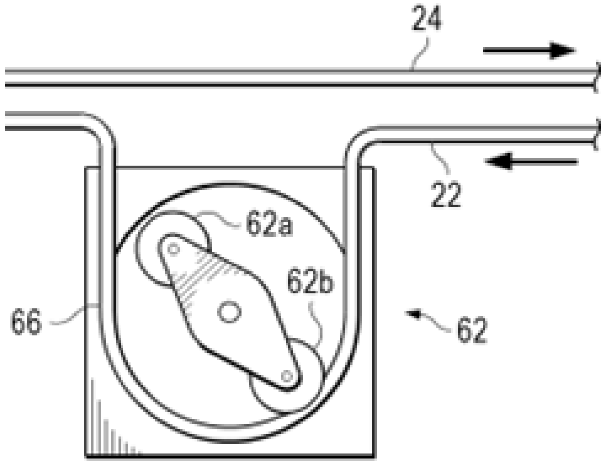


FIG. 15

Ridges



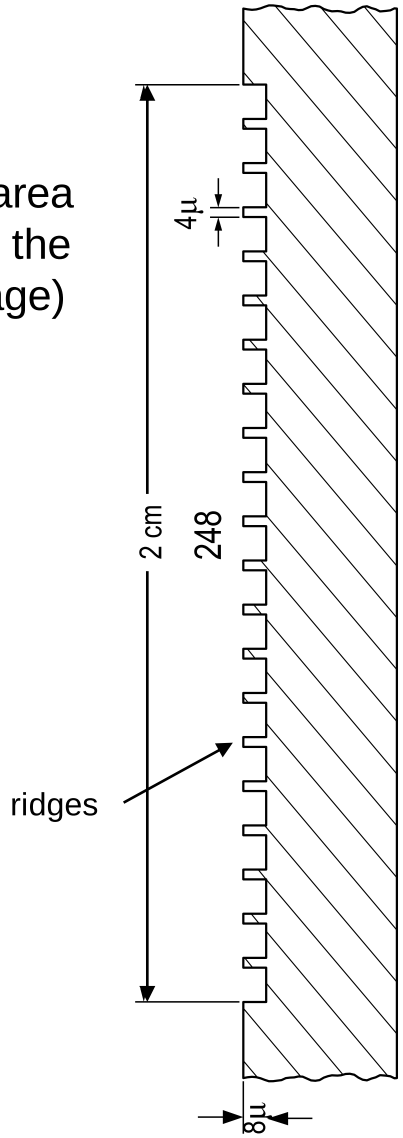
Pump (part of the apparatus)

Top view of the insertable cassette, the pump, and the two-lumen catheter.

Cassette Unit Continued

FIG. 11

Treatment area (oriented to the previous page)



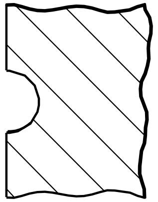


FIG. 13

Small flow channel

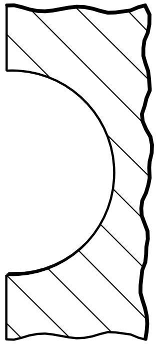
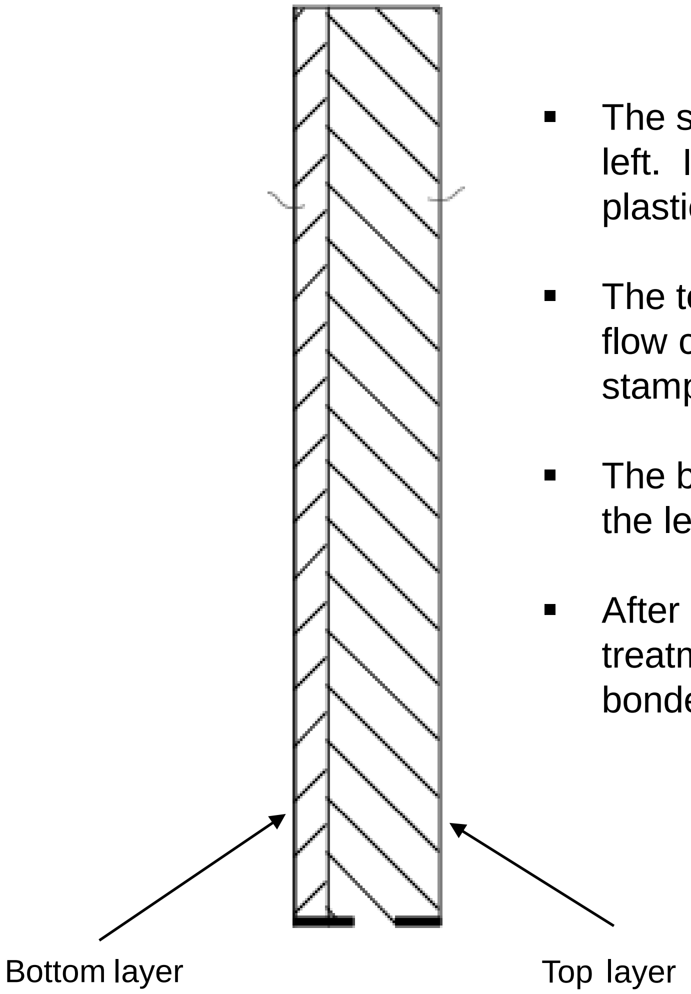


FIG. 12

Large flow channel

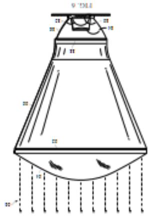
The treatment areas are very thin and have a large area. The ridges maintain the thin spacing over the large area, and do not impede flow.



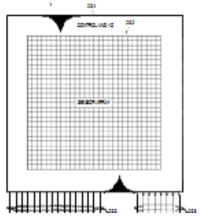
- The side of the cassette is shown to the left. It is formed from two layers of clear plastic.
- The top layer is several mm thick; the flow channels and treatment areas are stamped into it from the bottom.
- The bottom layer is very thin to facilitate the lensless imaging.
- After forming the flow channels and treatment areas, the top and bottom are bonded together.

Treatment Area

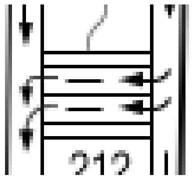
Individual stack



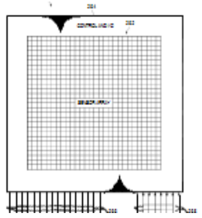
Single light source



Single liquid crystal array

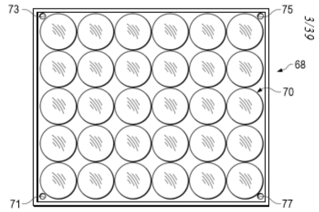


Single treatment area

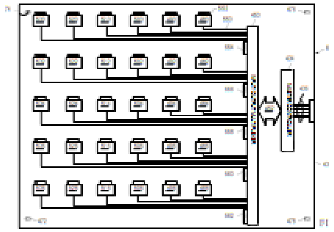


Single imager

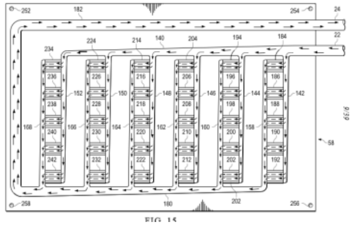
Complete array



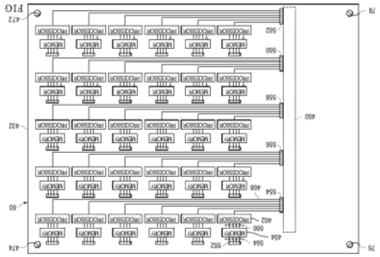
5 x 6 array of light sources



5 x 6 array of liquid crystal drivers



5 x 6 array of treatment areas



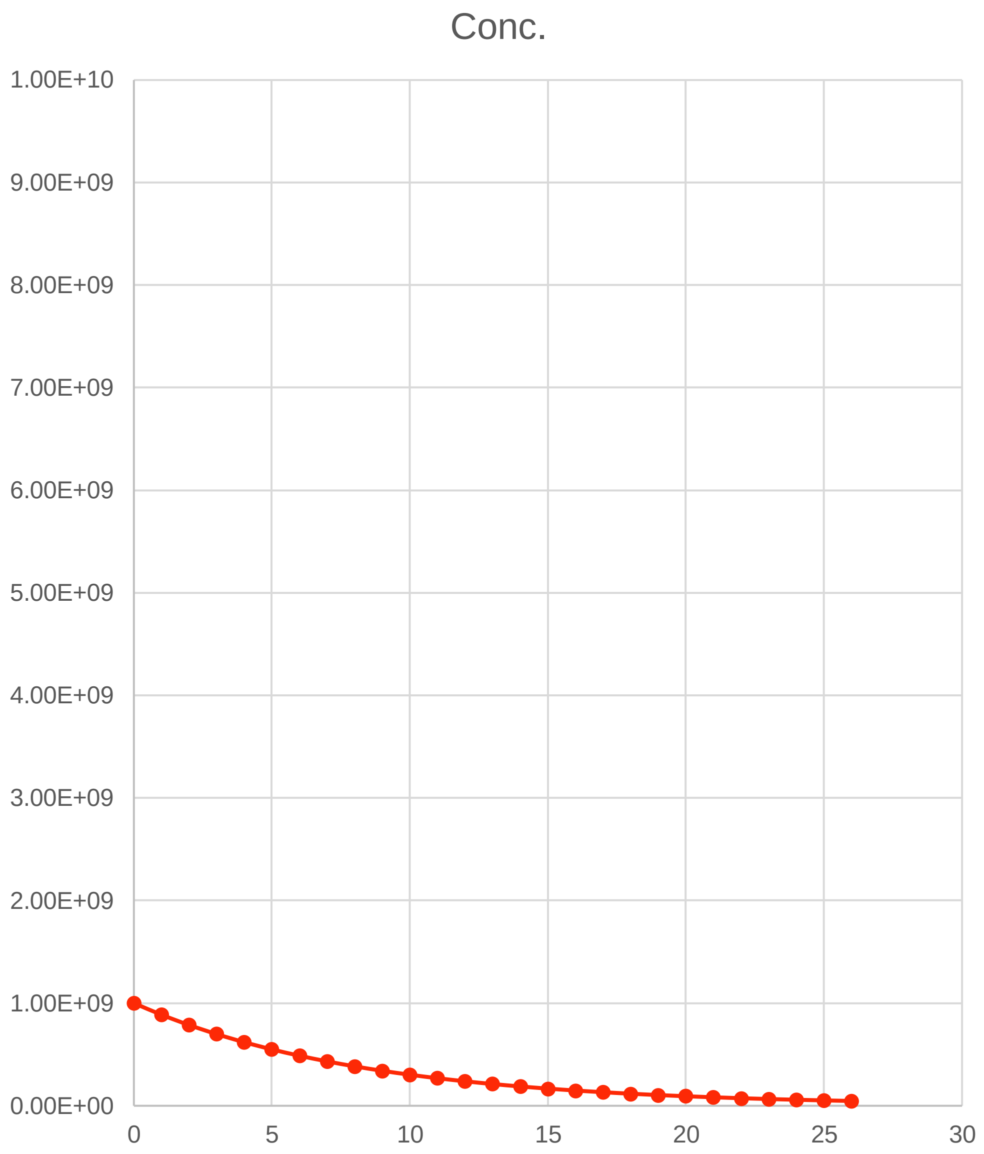
5 x 6 array of imager controllers

Each treatment area is a stack of collimated light source, liquid crystal layer, cassette, and imager.

- Collimated light source:
  Visible light for imaging; high-intensity UV for treatment
- High-resolution liquid crystal window:
  Passes light for analysis; blocks & passes UV for treatment
- Cassette treatment areas:
  Very thin to allow lensless imaging of blood
- High-resolution imager:
  Provides 1-bit images of blood cells & pathogens

Flow Rate

Computation of pathogen concentration in the blood vs. time (hrs)			time (hrs)	Conc.
			0	1.00E+09
Pathogen:	E-coli		1	8.87E+08
Doubling time in minutes at 37C	24.76		2	7.86E+08
Doubling time in hours	0.413		3	6.97E+08
Calculated growth time constant in hours	0.595		4	6.18E+08
Initial concentration	1.00E+09		5	5.48E+08
			6	4.86E+08
Patient blood volume in liters	5.0		7	4.31E+08
			8	3.82E+08
Treatment rate in liters/hour	9.0		9	3.39E+08
			10	3.00E+08
Calculated treatment time constant in hours	0.556		11	2.66E+08
			12	2.36E+08
			13	2.09E+08
			14	1.86E+08
			15	1.65E+08
			16	1.46E+08
			17	1.29E+08
			18	1.15E+08
			19	1.02E+08
			20	9.01E+07
			21	7.99E+07
			22	7.09E+07
			23	6.28E+07
			24	5.57E+07
			25	4.94E+07
			26	4.38E+07



Methods for Destroying Pathogen Cells

1. UV Light
2. Electric Field
3. Electric Current
4. Heat
5. Venting

Our Founders

Dale B. Nixon

Dale Nixon received a bachelor of science in electrical engineering degree with honors from the University of Arkansas and a Juris Doctor (Law) degree from the University of Texas. Mr. Nixon is a licensed attorney in the State of Texas and is a registered patent attorney with the US Patent Office. He served four years in the US Navy with the rank of Lieutenant in the Naval Security Group working in the field of electronic warfare.

In the legal field, he worked as a partner in the intellectual property law firm of Richards, Medlock and Andrews in Dallas, Texas and then as a partner with the international law firm Sidley Austin. His legal work includes extensive patent litigation in federal courts, patent license negotiations and licensing for major semiconductor companies and the drafting and prosecution of over 300 patent applications in the US Patent and Trademark Office.

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Dr. W. Milton Gosney

William Milton "Milt" Gosney, Jr., earned a B. S. degree at North Carolina State University, and M.S. and Ph.D. degrees at the University of California at Berkeley. He holds 14 patents in the field of semiconductor devices, processes and circuits. He is a Life Senior Member of the IEEE, and a registered Professional Engineer in Texas. He has served as an expert witness in over 100 patent-infringement cases.

He joined the faculty at Southern Methodist University as the Cecil and Ida Green Professor of Electrical Engineering in 1986. In 2006, Professor Gosney was recognized as an Altshuler Distinguished Teaching Professor, and also has received several Outstanding Professor Awards in Electrical Engineering. Prior to SMU, Professor Gosney worked in industry for 17 years at Texas Instruments and Mostek Corporation (now part of ST Microelectronics).

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Thank You